

Appl. No. : 09/776,232
Filed : February 02, 2001

REMARKS

Claims 38-51, 61 and 62 are pending in the present application. Claims 38 and 45 have been amended. In addition, new Claims 63-73 have been added. Support for new Claims 63-73 is found throughout the specification and the original claims, for example, on page 7, line 23 through page 8, line 14, page 25, line 9 through page 26 line 6; page 59, lines 11-16; page 60, lines 8-33; page 61, lines 1-6, page 61, lines 7-27. Thus, no new matter has been added to the application by entering this amendment. Accordingly, Applicant respectfully submits that the application is now in condition for allowance.

Pursuant to the USPTO Revised Format for Amendments, the amendments to the claims are shown by ~~striketrough~~ for deleted matter and underlining for added matter. No accompanying "clean" version has been supplied.

Rejection under 35 U.S.C. § 112, second paragraph

The Office Action has rejected Claims 38-51 and 61-62 under 35 U.S.C. § 112, first paragraph, alleging that the specification does not enable any person skilled in the art to which it pertains, or to which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In particular, the Office Action asserts that "the specification, while being enabling for a method of inducing LCM[V] specific CTL response in a mammal does not reasonably provide enablement for a method of inducing a CTL response as set forth in Claims 38-51 and 61-62 compris[ing] delivering a liquid comprising (1) *any* cell-free antigen, (2) *any* protein, (3) *any* peptide, (4) *any* microorganism, (5) *any* 'component' of a microorganism cell [] wherein said microorganism cell comprises a recombinant nucleic acid encoding or promoting expression of said undisclosed antigen for treating any disease." The Office Action cites various references for the proposition that the terms "antigen," "protein," and "peptide" without the amino acid sequence and SEQ ID NO have no structure, much less function.

To be enabling, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. M.P.E.P. § 2164.08 (citing *In re Buchner*, 929 F.2d 1557 (Fed. Cir. 1993)). Enablement "is not precluded even if

Appl. No. : 09/776,232
Filed : February 02, 2001

some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive.” *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986).

Applicants respectfully submit that specification teaches one of skill in the art how to perform the full scope of the claimed methods. Each of the pending claims includes a delivery step which includes, *inter alia*, delivering an “antigen” directly to a lymph node or lymph vessel. The specification teaches such delivery, for example, at page, 67, line 18 through page 70, line 11 and the Examples.

Also, the claimed methods are not limited to any particular antigen, and thus, *any* antigen can be used in the claimed methods. Additionally, the specification provides numerous exemplary antigens that can be used with the claimed methods. *See, e.g.*, Specification at page 27, line 14 through page 28, line 8, and Tables I - III. Performance of the claimed methods does not require a particular antigen protein structure or protein function as suggested in the Office Action. Structure and function are irrelevant to the immunogenicity of an antigen, as exemplified by the fact that those of skill in the art often use denatured proteins as antigens. Because the claimed route/mode of administration does not depend on protein structure or function, *any* antigen may be used. Thus, one of ordinary skill in the art can perform the claimed methods without undue experimentation.

In light of the foregoing amendment and remarks, Applicants submit that the specification reasonably provides enablement for a method of inducing a CTL response as set forth in Claims 38-51 and 61-62. Applicants respectfully request that the rejection under this section be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph -- Written Description

The Office Action has rejected Claims 38-51 and 61-62 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, it is alleged that “the specification does not reasonably provide a written description of a method of inducing a

Appl. No. : 09/776,232
Filed : February 02, 2001

CTL response as set forth in Claims 38-51 and 61-62 compris[ing] delivering a liquid comprising (1) *any* cell-free antigen, (2) *any* protein, (3) *any* peptide, (4) *any* microorganism, (5) *any* 'component' of a microorganism cell [] wherein said microorganism cell comprises a recombinant nucleic acid encoding or promoting expression of said undisclosed antigen for treating any disease."

To satisfy the written description requirement, a patent application must describe the invention in sufficient detail that one of skill in the relevant art could conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991). Possession may be shown in a variety of ways including description of an actual reduction to practice by describing testing of the claimed invention. M.P.E.P. § 2163 (citing *Enzo Biochem*, 296 F.3d 1316, 1326 (Fed. Cir. 2002)).

Applicants describe the claimed methods in sufficient detail that one of skill in the art could conclude that the applicants were in possession of the claimed invention at the time the application was filed. The claimed methods are directed to using any antigen and delivering the antigen to a mammal via a particular route/mode of administration, namely, directly to a lymph node or lymph vessel. Thus, the claimed invention is not limited to any particular antigen. Describing all antigens that could be used in this way is not the proper standard for written description of a method claim. Nevertheless, Applicants note that numerous exemplary antigens are disclosed throughout the specification, see for example, page 27, line 14 through page 28, line 8, and Tables I - III, which disclose hundreds of exemplary antigens. Moreover, in addition to listing numerous antigens contemplated for use in the claimed methods, the specification defines useful antigens as those "that stimulate[] the immune system of a mammal having a malignant tumor or infectious disease to attack the tumor and inhibit its growth or to destroy the pathogen causing the disease." Specification at page 22, lines 6-8. Therefore, the specification describes the full scope of the claimed methods, including numerous antigens that can be used with the methods.

In light of the foregoing remarks, Applicants submit that Claims 38-51 and 61-62 meet the written description requirement of 35 U.S.C. § 112. Applicants respectfully request withdrawal of this rejection.

Appl. No. : 09/776,232
Filed : February 02, 2001

Rejection under 35 U.S.C. § 112, first paragraph -- New Matter

The Office Action has rejected Claims 38-51 and 60-62 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Specifically, the Office Action asserts that the “cell-free” in Claims 38 and 45 represents a departure from the specification and the claims as originally filed.

Applicants respectfully disagree that the “cell-free” in Claims 38 and 45 represents a departure from the specification and the claims as originally filed as the specification provides numerous examples of cell-free antigens for use in the claimed methods. Nevertheless, in order to advance prosecution of the application, Applicants have amended Claims 38 and 45 to remove the term “cell-free.” In light of this amendment, Applicants respectfully request that the rejection under this section be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph -- Indefiniteness

The Office Action has rejected Claims 49, and 60-61 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office Action alleges that “component of a microorganism cell” in Claim 49 is indefinite and ambiguous because it is not clear if the “component” is referring to the DNA, the protein, or the cell wall of the microorganism or cell. In addition, the Office Action asserts that the “device external to the animal” in Claims 60 and 61 is indefinite and ambiguous because it is not clear if the device is a needle, a syringe, a catheter or osmotic pump or insulin pump.

Regarding the objection to the term “component” in Claim 49, Applicants respectfully disagree and submit that the term “component” clearly establishes the metes and bounds of the claim. The ordinary meaning of the term “component” is “a constituent element, as of a system.” Accordingly, Applicants respectfully submit that one skilled in the art having read Applicants’ disclosure could readily determine the metes and bounds of the claimed invention. Specifically, a person of skill in the art, reading the phrase “component of a microorganism cell” would recognize that any constituent element of a microorganism cell capable of inducing an immune response would be encompassed by this phrase.

Appl. No. : 09/776,232
Filed : February 02, 2001

Regarding the objection to the phrase “device external to the animal” in Claims 60 and 61, Applicants respectfully disagree and submit that it is clear from the specification, for example, at page 64, lines 1-8, that a “device external to the animal” is intended to mean a device positioned outside the patient’s body. In addition to defining what is meant by the term, Applicants provide numerous examples of external devices useful in the invention, see for example, the specification at page 64, line 1 through page 65, line 13, including Table IV. Accordingly, Applicants respectfully submit that one skilled in the art having read Applicants’ disclosure could readily determine the metes and bounds of the claimed invention.

Rejections Under 35 U.S.C. § 102

Claims 38-42, 45-46, and 50 were rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Issekutz, *Clin. Exp. Immunol.* 56:515-23 (1984) (Issekutz). Additionally, Claims 38, 40-41, 45-46, and 50-51 were rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Grohmann et al., *J. Immunol. Methods* 137:9-16 (1991) (Grohmann). Finally, Claims 38, 40-41, 45 and 50 were rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Klavinskis et al., *J. Immunol.* 157:2521-27 (1996) (Klavinskis).

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). “Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Independent Claims 38 and 45 recite, in relevant part, delivering an antigen “directly to a lymph node or lymph vessel of the mammal.” Thus, direct delivery to the lymph node or lymph vessel is a meaningful feature of the claims, and therefore, must be considered in evaluating the patentability of the claims. Applicants respectfully submit that the cited references do not teach every element of the claims because none of the references teaches, *inter alia*, delivering antigen

Appl. No. : 09/776,232
Filed : February 02, 2001

directly to a lymph node or lymph vessel. Accordingly, Applicants submit that the cited references do not anticipate the claims.

Issekutz

The Office Action asserts that Issekutz teaches a method of inducing a CTL response such as vaccinia virus specific CTL response in a mammal such as sheep comprising injecting a single bolus dose of a liquid comprising a cell-free antigen such as live vaccinia virus (microorganism) directly into the draining site of the cannulated lymph node and the reference lymph node inherently maintains the reference antigen in the mammal's lymphatic system over time to induce a CTL response.

Issekutz discloses subcutaneous injection of the vaccinia virus into the drainage site of the cannulated lymph node. See Issekutz at page 516-517, and 521. A skilled artisan would understand a subcutaneous injection to mean one that is given just beneath the skin to the space between the skin and the underlying tissue, typically using a very small needle that is long enough to penetrate the skin but not the underlying muscle.

One of skill in the art would appreciate that the "drainage site" of a cannulated lymph node is the region of tissue from which a substance migrates, or "drains," to a particular lymph node. Moreover, those of skill in the art would understand lymph node drainage to mean the flow of a substance or lymph from an area of tissue into a particular lymph node. Accordingly, subcutaneous injection into a drainage site of a lymph node, as performed in Issekutz, indicates that the vaccinia virus was deposited to an area of tissue just below the skin where it later migrated into a particular lymph node. Thus, those of skill in the art would recognize that Issekutz utilized a form of indirect delivery of vaccina virus to the lymph node or lymph vessel.

In contrast, the instant claims utilize direct delivery to a lymph node or lymph vessel. In the case of administration of antigen via intra lymph node injection, a needle long enough to penetrate the skin as well as any other tissues between the skin and the lymph node of interest such that the tip of the needle is inserted into the lymph node or lymph vessel would be used. See, e.g., Specification at page 67, lines 18-20 and page 70, lines 8-11. Applicants clearly distinguish subcutaneous and intra lymph node injections throughout the specification, for example, in reporting their observation that antigen delivered directly to the lymph node was 100 to 1000 times more efficient at inducing a CTL response compared to conventional subcutaneous

Appl. No. : 09/776,232
Filed : February 02, 2001

delivery. *See, e.g.*, Specification at page 13, line 31 through page 14, line 1, page 63, lines 24-26, and page 69, lines 25-27. As discussed above, Issekutz discloses subcutaneous delivery of antigen to a drainage site. Thus, Issekutz does not teach or suggest direct delivery of the antigen to a lymph node or lymph vessel as set forth in the pending claims of the instant application. On the contrary, Issekutz teaches away from direct delivery by instead teaching subcutaneous injection into an area of lymphatic drainage. Accordingly, Applicants respectfully submit that Issekutz cannot anticipate Claims 38-42, 45-46, and 50.

Because Issekutz does not teach, either directly or inherently, each and every element of the claimed invention, Claims 38-42, 45-46, and 50 are novel under 35 U.S.C. § 102(b). Accordingly, Applicants respectfully request that this rejection be withdrawn.

Grohmann

The Office Action alleges that Grohmann teaches “a method of inducing a CTL response in a mammal such as mice comprising injecting minute amounts of cell-free antigen such as lysate of highly immunogenic murine lymphoma cells bound to nitrocellulose directly into the lymphatic vessel such as the spleen.”

Grohmann discloses the surgical implantation of a nitrocellulose-bound protein into the spleen in order to elicit a humoral and a cellular immune response. *See* Grohmann at page 10. Specifically, antigenic peptide adsorbed on a membrane strip was deposited in the spleen of a mouse through a small incision in the splenic capsule. *Id.* Grohmann discloses surgically implanting nitrocellulose-bound antigen into the spleen only and does not teach or suggest surgically implanting the nitrocellulose-bound antigen into any other component of the lymphatic system.

As discussed above, the pending claims are directed to delivery of antigen directly to lymph nodes or lymph vessels. Applicants disclose in the specification that the lymphatic system includes lymph, lymphocytes, lymph vessels, lymph nodes, tonsils, the spleen, the thymus gland, and bone marrow. Specification at page 7, lines 7-9. Thus, the instant specification distinguishes between the spleen, lymph nodes, and lymph vessels, recognizing each as a distinct component of the lymphatic system. *See e.g.*, Specification at page 6, lines 20-21, page 7, lines 7-9, and page 67, lines 16-18. Moreover, Applicants disclose that one important functional difference between the lymph nodes and the spleen is that the lymph nodes filter lymph and the

Appl. No. : 09/776,232
Filed : February 02, 2001

spleen filters blood. Specification at page 12, line 27. As discussed above, Grohmann discloses surgical implantation of antigen into the spleen only. Thus, Grohmann does not teach direct delivery of antigen to a lymph node or lymph vessel. Accordingly, Grohmann does not anticipate Claims 38, 40-41, 45, and 50.

Furthermore, independent Claims 38 and 45 recite, in relevant part, “delivering a liquid comprising a[n] antigen directly to a lymph node or lymph vessel of the mammal.” Thus, the use of a liquid to deliver the antigen is a meaningful feature of the claims, and therefore must be considered in evaluating the patentability of the claims. As discussed above, Grohmann discloses the surgical implantation of an antigenic peptide adsorbed on a membrane strip. *Id.* Thus, Grohmann does not teach the use of a liquid to deliver the antigen directly to the lymphatic system of a mammal. On the contrary, Grohmann teaches away from the use of a liquid to deliver the antigen directly to the lymphatic system of a mammal by instead teaching the surgical implantation of an antigenic peptide adsorbed on a membrane strip. Accordingly, Grohmann does not anticipate Claims 38, 40-41, 45, and 50.

Because Grohmann does not teach each and every element of the claimed invention, Applicants respectfully request reconsideration and withdrawal of this rejection.

Klavinskis

The Office Action asserts that Klavinskis teaches a method of inducing a CTL response in a mammal such as Rhesus macaques by injecting subcutaneously in the proximity of the iliac lymph node of the macaques a liquid comprising a cell-free antigen such as SIVp27:Ty-VLP peptide mixed with aluminum hydroxide that induce a virus-specific CTL response.

As the Office Action notes, Klavinskis teaches subcutaneous injection of the hybrid virus-like particles in the proximity of the iliac lymph node. *See* Klavinskis at page 2522. As discussed above, subcutaneous injection of antigen is a form of indirect delivery of antigen to a lymph node. In contrast, the rejected claims concern the direct delivery of antigen to a lymph node or lymph vessel. Because Klavinskis does not teach or suggest direct delivery of the antigen to a lymph node or lymph vessel, the reference does not anticipate the Claims 38, 40-41, 45 and 50. Accordingly, Applicants respectfully request that this rejection in view of Klavinskis be withdrawn.

Appl. No. : 09/776,232
Filed : February 02, 2001

For all of the above reasons, Applicants respectfully request withdrawal of all rejections under 35 U.S.C. § 102(b), and allowance of the pending application.

Rejections Under 35 U.S.C. § 103(a)

Claims 38, 43, 45-46, 48-49, and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Issekutz as applied to the claims under § 102(b) above in view of Bot et al, U.S. Patent No. 6,204,250 B1 (the '250 patent), Coupey et al., *Cytokine* 5(6):564-69 (1993) (Coupey) and Zinkernagel et al., *Immunol. Rev.* 156:199-209 (1997) (Zinkernagel).

In addition, Claims 38, 45-47, and 60-62 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Issekutz in view of Carson et al., U.S. Patent No. 5,679,647 (the '647 patent), Bauer et al., U.S. Patent No. 5,830,452 (the '452 patent), Coupey and Zinkernagel.

To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Third, the prior art reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Independent Claims 38 and 45 are directed to delivering antigen "directly to a lymph node or lymph vessel of the mammal." Thus, direct delivery to a lymph node or lymph vessel is a meaningful feature of the claims, and therefore, must be considered in evaluating the patentability of the claims. Issekutz is applied as in the rejection under 35 U.S.C. § 102(b) above. As discussed in response to that rejection, Issekutz teaches subcutaneous injection of the vaccinia virus into the drainage site of the cannulated lymph node. *See* Issekutz at page 516-517, and 521. Thus, Issekutz does not teach direct delivery of the antigen to a lymph node or lymph vessel. On the contrary, Issekutz teaches away from such direct delivery by instead teaching subcutaneous delivery which is, at best, an indirect route to a lymph node or lymph vessel. A person of ordinary skill in the art, reading Issekutz, would be motivated to employ a subcutaneous route of delivery, and would not be motivated to make the claimed combination. A reference that teaches away from the invention cannot be used in a *prima facie* case of obviousness, because it is improper to combine references where the references teach away from

Appl. No. : 09/776,232
Filed : February 02, 2001

the combination. M.P.E.P. § 2145(X)(D)(2) (citing *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983)). Accordingly, Applicants respectfully submit that the PTO has failed to establish a *prima facie* case of obviousness due to its reliance upon Issekutz as a primary reference. Thus, the claims are not obvious in view of the asserted combinations of references.

For the foregoing reasons, Applicants respectfully submit that the pending claims are not obvious under 35 U.S.C. § 103(a) in view of the cited references, and hereby request that this rejection be withdrawn.

Claims 38-39, 43, 45-49, and 60-62 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Grohmann in view of the '647 patent,¹ the '452 patent, Coupey and Zinkernagel.

As discussed above, independent Claims 38 and 45 are directed to delivering an antigen "directly to a lymph node or lymph vessel of the mammal." Thus, direct delivery to a lymph node or lymph vessel is a meaningful feature of the claims, and therefore, must be considered in evaluating the patentability of the claims. Grohmann is applied as discussed in the rejection under 35 U.S.C. § 102(b) above. As discussed in the response to that rejection, Grohmann discloses the surgical implantation of a nitrocellulose-bound protein into the spleen. Grohmann at 10. Thus, Grohmann does not teach or suggest direct delivery of a liquid comprising an antigen to a lymph node or lymph vessel. On the contrary, Grohmann teaches away from direct delivery of a liquid comprising an antigen to a lymph node or lymph vessel by instead teaching surgical implantation of nitrocellulose-bound antigen into the spleen. A reference that teaches away from the invention cannot be used in a *prima facie* case of obviousness, because it is improper to combine references where the references teach away from the combination. M.P.E.P. § 2145(X)(D)(2) (citing *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983)). Accordingly, Applicants respectfully submit that the PTO has failed to establish a *prima facie* case of obviousness due to its reliance upon Grohmann as a primary reference. Thus, the claims are not obvious in view of the asserted combinations of references.

¹ Applicants note that the Office Action mentions the '250 patent in connection with this rejection, but instead refers to the '647 patent in discussing the rejection.

Appl. No. : 09/776,232
Filed : February 02, 2001

For the foregoing reasons, Applicants respectfully submit that Claims 38-39, 43, 45-49, and 60-62 are not obvious under 35 U.S.C. § 103(a) in view of the cited references, and hereby request that this rejection be withdrawn.

Claims 38, 43, 45, 48, 49, and 60-62 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Klavinskis in view of the '250 patent, Lane et al, U.S. Patent No. 5,696,079 (the '079 patent), the '452 patent, Coupey, and Zinkernagel.

As discussed above, independent Claims 38 and 45 are directed to delivering an antigen "directly to a lymph node or lymph vessel of the mammal." Thus, direct delivery to a lymph node or lymph vessel is a meaningful feature of the claims, and therefore, must be considered in evaluating the patentability of the claims. Klavinskis is applied as in the rejection under 35 U.S.C. § 102(b) above. As discussed above, Klavinskis, like Issekutz, teaches subcutaneous injection of antigen. Thus, Klavinskis does not teach direct delivery of the antigen to a lymph node or lymph vessel. On the contrary, Klavinskis teaches away from such direct delivery by instead urging subcutaneous delivery which is, at best, an *indirect* route to a lymph node or lymph vessel. A reference that teaches away from the invention cannot be used in a *prima facie* case of obviousness, because it is improper to combine references where the references teach away from the combination. M.P.E.P. § 2145(X)(D)(2) (citing *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983)). Accordingly, Applicants respectfully submit that the PTO has failed to establish a *prima facie* case of obviousness due to its reliance upon Klavinskis as a primary reference. Thus, the claims are not obvious in view of the asserted combinations of references.

For the foregoing reasons, Applicants respectfully submit that Claims 38, 43, 45, 48, 49, and 60-62 are not obvious under 35 U.S.C. § 103(a) in view of the cited references, and hereby request that this rejection be withdrawn.

Appl. No. : 09/776,232
Filed : February 02, 2001

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the application is now in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain, or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: February 23, 2004

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